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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,851	08/06/2004	Chad C. Steele	BC-0112-P05	4850
24994	7590	08/11/2005	EXAMINER	
GAMBRO, INC PATENT DEPARTMENT 10810 W COLLINS AVE LAKEWOOD, CO 80215			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	10/710,851	Applicant(s)
Examiner	Patricia M. Bianco	STEELE ET AL.
		Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on 25 May 2005.
- 2a)  This action is FINAL. 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 1-23 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-23 is/are rejected.
- 7)  Claim(s) 15 and 18 is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All b)  Some \* c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/6/04 &amp; 9/28/04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

## **DETAILED ACTION**

### ***Election/Restrictions***

After reviewing applicant's arguments and upon further review of the claims, the restriction requirement has been withdrawn. All of the claims, 1-23, have been examined on the merits.

### ***Claim Objections***

Claims 15 & 18 are objected to because of the following informalities: in each claim it appears that the word "and" is missing after the word *condition* in line 5 of each claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prince (5,178,603) in view of Lyle et al. 5,956,023).

Prince teaches of an apheresis system and method of performing apheresis wherein the system is controlled by a control system. The control system performs

multiple checks and balances on the performance of the system, such as pump rate, blood flow, and pressure values, at various points in the system. The system measures a value of a desired performance, determines the relationship to preset values, which may be represented graphically, and then alters the system based on the results. (See entire description) Prince also teaches that a sensor may be used to monitor the system. Prince does not teach explicitly of operational control and input by an operator of the system at the checkpoints during procedure. However, it is reasonable to one of ordinary skill in the art that some operator input would be likely if not expected for the system to be programmed and/or to override the system at specific instances.

Lyle et al. (hereafter Lyle) teaches of medical processing device having a control system that can be operator controlled or automatic, depending on preference. The medical device is a separation system 10 for processing whole blood into its components (i.e. apheresis) includes a centrifuge 12, a disposable fluid processing assembly (i.e. at least one blood passageway), a pressure monitor (i.e. a sensor) and a controller 18 for presiding over the system and its operation. The system controller monitors the functions and overall processes control of the blood separation system and its components via a main processing unit (MPU). The MPU employs a microprocessor that allows for real-time monitoring and tasking including a timer for preempting the steps carried out in the process. The MPU is in communication to receive input and deliver output to the main parts of the system, such as the centrifuge, pumps, tubing, sensor etc.. The MPU may have an interactive operator interface for the operator to view, comprehend, troubleshoot and change the function and performance of the

system. The display may be in alphanumeric or graphical images along with a voice prompt to instruct the operator to take action. The MPU has a status region that continuously shows prescribed procedure-dependent information and general information to keep the operator apprised of the status of the process. The operator may use the working region of the MPU to monitor and change aspects of the ongoing process. The operator may use the interface of the MPU to find and select any of detailed procedures, functions and options of the system. The operator may perform these functions using touch activation.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the control system of Prince with the feature of Lyle et al. to allow for the operator to have greater control of the system.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 6, 8, & 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims {insert patent claim #s} of U.S. Patent No. 6,497,674. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are a broader recitation of the invention than that of the issued patent, including all of the same limitations. Since a broad interpretation of the patent claims includes the invention claimed in the application, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the '674 patent. The claims match up as follows:

Application claims 6/4/1 are equivalent to patent claim 1

Application claims 10/8/1 are equivalent to patent claim 2.

Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 & 5-7 of U.S. Patent No. 6,497,674 in view of Patent 5,941,842. The claims match up as follows: Application claims 2-5 are equivalent to patent claims 7/6/5/11. The application claims recite the invention as claimed in patent '674, except for specifically teaching that the graphical representation comprises text. The invention disclosed in patent 5,941,842 discloses the same inventive method and specifically teaches that the graphical representation comprises text. Since it is graphical representation incorporates text, such a modification would have been an obvious design choice.

***Conclusion***

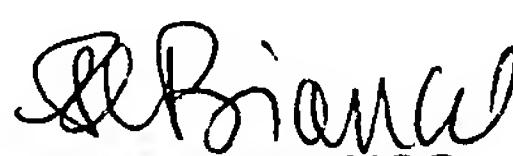
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 3<sup>rd</sup>, 2005

Patricia M Bianco  
Primary Examiner  
Art Unit 3761

  
PATRICIA BIANCO  
PRIMARY EXAMINER